

## Frequently Asked Questions Quality Improvement Initiative versus Research

### **Can the Core Data initiative be considered a Quality Improvement (QI) Initiative by your site?**

While definitions of Quality Improvement (QI) Initiatives are variable, a recent article in the Journal of the American Medical Association by Caserat et. al provides some guidance (Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications. J Am Med Assoc 2000;283:2275-2280). These authors define quality improvement initiatives as “cycles of interventions that are linked to assessment that have the goal of improving the process, outcome and efficiency of care.” The design and goals of the NCTSN Core Data Set initiative corresponds with this definition.

Beyond this, the authors also raise two major questions that help distinguish whether project is a QI initiative or research:

#### **(1) Are the majority of subjects expected to benefit from the knowledge gained?**

Yes. Beyond pure chart extraction of core data, the NCTSN Core Data Set initiative will collect information pertaining to interventions that are linked to assessment and the improvement of the process, outcome and efficiency of care. The goal of the NCTSN Core Data Set initiative is to improve clinical outcomes of traumatized children presenting at network sites through early implementation and improved utilization of evidenced-based practices.

#### **(2) Will making the results generalizable require any additional risks or burdens on the children?**

No. the NCTSN Core Data Set initiative does not dictate or require any patient treatments. Rather this initiative will collect data about the care currently being administered to traumatized children. It will also explore whether certain types of treatments (particularly evidenced-based practice [EBP]) are related to significantly better outcomes than other forms of treatment and disseminate this information to the network for use across all participating sites.

The authors of the article referenced above felt that if the answers to the first and second questions were YES and NO, respectively, then the project should be considered a QI initiative and not research.

If your site considers the answers to the first and second questions to be YES and NO respectively, then your site will likely view this initiative as a Quality Improvement Initiative.

If your site considers the answers to the first and second questions to be NO and YES respectively, your site may view this initiative as research. Even if your site views this initiative as research, it may decide to waive informed consent if certain requirements are met.

We, DCRI, are not requesting a waiver of informed consent for this Quality Improvement Initiative because:

- the data collected involves no greater than minimal risk,
- waiving the informed consent will not adversely affect the subjects' rights and welfare,
- the type of information gathered through these data collection efforts impacts future patient care and not that of the subjects in the database,
- however, it is “practical” to collect these data without a waiver, even though in some cases informed consent may be difficult to obtain.